OrthoScan HD
8585 E. Hartford Dr., Suite 900, Scottsdale, AZ 85255

2 September 2005

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Variance Application:

In accordance with 21 CFR 1010.4, OrthoScan, Inc. hereby submits application for a variance from the source-skin distance requirement of the performance standard for fluoroscopic equipment [21 CFR 1020.32(g)], as it applies to the OrthoScan, 510(k) # K051754.

The following information is provided in support of this application:

1. **Description of the product and its intended use:**
   The OrthoScan, manufactured by OrthoScan, Inc. is a small C-arm configuration, image-intensified fluoroscopic system. OrthoScan is intended to provide the physician with fluoroscopic visualization of the patient during surgical orthopaedic procedures and diagnostic examinations.

A summary of relevant OrthoScan specifications is provided as follows:

OrthoScan	Specifications
X-Ray Tube/Generator	
High Voltage Range	40 to 80 kVp
Tube Current Range	30 μA to 110 μA (0.030 to 0.110 mA)
Automatic Dose Rate Control	yes
Entrance Exposure Rate (max.)	3.6R/min. at 10 cm
Focal Spot	0.05 mm (50 micron)
Collimator	2 position fixed, 4" and 6"
Image Intensifier	4" and 6-inch field of view
Source-Image Distance	47cm (18.5 inch)

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2. **An explanation of how compliance with the applicable standard would restrict or be inappropriate for the intended use:**
Like the other commercially available mini C-arms (FluoroScan, Lunar, and GE OEC), the OrthoScan offers a compact and economical imaging system that is well suited for orthopaedic surgery and diagnostic examination.

   These surgical applications require that the open area between the x-ray head and the image intensifier be large enough to allow the physician to manipulate surgical tools. This is not possible if the minimum source-skin distance (SSD) is limited to that required by the performance standard, i.e. 30 centimeters for mobile fluoroscopes or 20 centimeters for fluoroscopes intended for specific applications.

3. **A description of the manner in which it is proposed to deviate from the requirements of the applicable standard:**
The OrthoScan deviates from the performance standard by providing a SSD of less than 20 centimeters as required for fluoroscopes intended for specific applications. We propose that the OrthoScan provide SSD of 10 cm.

4. **A description of the advantages to be derived from such deviation:**
A reduction in the minimum SSD allows the OrthoScan to utilize a relatively short source-image distance (SID) of 47 centimeters. Consequently, the x-ray technique factors necessary to produce high quality diagnostic images are proportionately lower than those employed by a conventional fluoroscope. For example, the x-ray tube current range of the OrthoScan is 0.030 to 0.110 mA (30-110 μA) compared to 0.2 to 5.0 mA, typical of a conventional mobile C-arm. This results in comparable entrance dose rates when the patient anatomy is positioned as close as possible to the image intensifier.

5. **An explanation of how alternate or suitable means of radiation protection will be provided:**
Suitable means of radiation protection is provided by constraints on the design and supplemental information provided to users.

   The minimum SSD of 10 cm centimeters is established by the collimator enclosure that is permanently attached to the x-ray tube housing.

   The user manuals contain supplemental information and precautions that may be necessary because of the shortened SSD.

6. **The period of time it is desired that the variance be in effect:**
OrthoScan requests the variance be in effect for a five-year period.

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7. **Sample of label to be placed on each OrthoScan device:**
   "This Device has been granted a F.D.A. variance from the source-skin distance requirements of the performance standard for fluoroscopic equipment [21 CFR 1020.32(g)], Variance #: _____, Dated: _____."

8. **Other information required by regulation or by the Director, Center for Deices and Radiological Health, to evaluate and act on the application:**
   Radiation data was measured using a Cardinal Health Triad Model 35050AT (S/N 0000000081) Calibrated 12/29/04 due 12/29/05 with a Model 90635B ion chamber (S/N 0000107597) with the same calibration dates.

If you require additional information to evaluate and act upon this application, please contact me at 480-503-8010.

Sincerely,
OrthoScan, Inc.

Larry S. Grossman
Chairman